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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/804,745

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M19-106

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06/09/2009

EXAMINER

FISHER, ABIGAIL L

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1616

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/804,745	<b>Applicant(s)</b> COHN ET AL.	
	<b>Examiner</b> ABIGAIL FISHER	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7 and 89-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-7 and 89-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt of Amendments/Remarks filed on February 13 2009 is acknowledged. Claims 4-5 and 8-88 were/stand cancelled. Claim 93 was amended. Claims 94-102 were added. Claims 1-3, 6-7 and 89-102 are pending.

### *Claim Interpretation*

Claim 1 and the claims that depend from claim 1 contain the transitional language "consisting essentially of". For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *PPG Industries Inc. V Guardian Industries Corp.* 48 USPQ2d 1351 (Fed. Cir. 1998) and *In re De Lajarte* 337 F.2d 870, 143 USPQ 256 (CCPA 1964) **See MPEP 2111.03.**

The instant specification does not define the term "consisting essentially of" in a manner that would allow one skilled in the art to determine what basic and novel characteristics are being materially affected.

### ***Claim Objections***

The objection of claim 93 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is **withdrawn** in light of Applicants' amendments filed on February 13 2009.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-3, 6-7 and 89-93 under 35 U.S.C. 103(a) as being unpatentable over Spenlehauer et al. (US Patent No. 5683723, cited in the Office action mailed on 8/14/07) in view of Domb et al. (5578325) is **withdrawn** in light of Applicants' arguments filed on February 13 2009 in which Domb utilizes cross-linking agents but the hydrophilic and hydrophobic copolymers are not bound to each other.

**Claims 1-3, 6-7 and 89-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebato et al. (US Patent No. 5525671) in view of Gref et al. (WO 95/03357, cited on PTO Form 1449).**

#### **Applicant Claims**

Applicant claims a polymeric composition consisting essentially of cross-linked AB diblocks where A is a polyester unit and B is a polyoxyalkylene polymer which is end-capped with a non-reactive group.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Ebato et al. is directed to production of lactide copolymer. The polymers comprise a lactide (column 9, lines 42-58) and a hydroxyl-containing polymer. The lactide copolymers obtained therefrom have a broad range of properties from soft to rigid. The hydroxyl-containing polymer preferably include polyester or polyoxyalkylene ethers having a hydroxyl groups at a terminal. Lactide copolymers obtained from these polymers have a block structure (column 9, lines 59-67). Copolymerization of a lactide

with hydroxyl-containing polymers rests in product of lactide copolymers having various properties and a high molecular weight. The rate of reaction of this copolymerization is equal to that obtained in homopolymerization because the hydroxyl group possessed by the starting polymer acts for control of chain transfer in chain propagation (column 10 lines 8-24). Suitable diols include ethylene glycol, propylene glycol, etc. (column 11, lines 19-23). It is taught that a polyfunctional isocyanate such as hexamethylene diisocyanate and/or polyfunctional acid anhydride can be added in the production of the copolymer. The polymer chain is then cross-linked to produce a lactide copolymer having a further increased molecular weight (columns 13-14, lines 65-67 and 1-7).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Ebato et al. do not specify that the hydroxyl containing polymer is end-capped with a methyl group. However, this deficiency is cured by Gref et al.

Greg et al. is directed to biodegradable particles. Polymers include copolymers of PEG-PLGA (figures). It is taught that in the preparation of diblock polymers polyalkylene glycols such as poly(ethylene glycol) is end blocked with methyl, monomethoxy polyalkylene glycol, and then polymerized with polymers such as D,L-lactide. It is taught that when forming triblocks such as PLGA-PEG-PLGA, then the PEG contains two end hydroxyl groups (pages 10-11, lines 33-37 and 1-24).

**Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Ebato et al. and Greg et al. and utilize end-capped polyethylene glycol

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such as monomethoxy polyethylene glycol. One of ordinary skill in the art would have been motivated to utilize end blocked polyethylene glycol in order to form diblocks of lactide and polyethylene glycol based on the teachings of Greg et al. One of ordinary skill in the art would have been motivated to utilize an end-capped PEG in order to form diblock copolymers as utilizing EPG comprising both ends with free hydroxyl groups forms triblock copolymers.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Ebato et al. and Greg et al. and utilize the cross linking agent hexamethylene diisocyanate. One of ordinary skill in the art would have been motivated to utilize the cross-linking agent hexamethylene diisocyanate in order to manipulate the molecular weight of the lactide copolymer as taught by Ebato et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher  
Examiner  
Art Unit 1616

AF

*/Mina Haghighatian/  
Primary Examiner, Art Unit 1616*